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HAI AP News

Penang, Malaysia
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HAI AP Est. 1981

Health Action International (HAI) was formally founded in Geneva in 1981 and coordinated from Penang by Action for Rational Use of Drugs in Asia (ARDA). In 1995 Health Action International Asia Pacific (HAI AP) was formed as a collaborative network in the Asia Pacific Region to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy. HAI AP is committed to strive for health for all now. *HAI AP News* is the organ of Health Action International – Asia Pacific and presents the happenings in the regional campaigns for more rational and fairer health policies and carries material in support of participants' activities.

In this issue

This year, 2021, we celebrate 40 years with HAI /HAIAP. We are celebrating our 40th anniversary at a special virtual gathering on May 29, 2021 at 7 pm Penang time. We will hear from three of our founders – Dato' Seri Anwar Fazal, Dr Mira Shiva and Dr Zafrullah Chowdhury and our HAIAP Governing Council Chair – Dr Niyada Kiatying Angsulee. We will also hear short reports from HAIAP partners in a range of countries - highlighting the breadth of interest and activities in the field. In addition, in this 40th year, the Olle Hansson Award will be revived and a fellowship award will also be established for a younger person activist.

During the year we will work towards producing a book that will be a chronicle of the life of HAIAP - which evolved from Action for Rational Drugs in Asia (ARDA) - from 1981 -2021; but particularly since 2006 when we celebrated 25 years and launched *Fast, Furious and Flexible* conceived and produced by Dr Kumariah Balasubramaniam and edited by Radha Holla. Members will be asked to contribute.

We look forward to being in touch with our HAIAP family and friends.

In this edition, we look at many issues that have an impact on access to medicines, vaccines and health technologies, particularly during the current COVID-19 pandemic.

We note that WHO has chosen the Health Worker to be the focus for 2021 - the Year of the Health Worker.

We feature a very comprehensive article in the Bulletin of the World Health Organisation by staff from the Department of Disease Control, Ministry of Public Health, Bangkok, Thailand, and the Thai International Health Policy Program, Ministry of Public Health, that highlights the important role of health workers in Thailand's response to COVID-19.

Finally we share a report by Ms Y Mapalagama of a project undertaken for the Students Involved in Rational Health Activities (SIRHA)- a group of Sri Lankan medical students dedicated to increasing awareness of rational health care.

HAIAP 40th Anniversary – 1981 -2021

We will be having a virtual celebration on May 29 at 7 pm Penang time; and a book that features historic events and plans for the future will be released later in the year.

[Many thanks to Dato' Seri Anwar Fazal for much of the information re-produced here. Ed.]

The birth of Health Action International (HAI) emerged from several streams of thinking, planning, and action – locally and globally.

Firstly, the **International Organisation of Consumers Unions (IOCU),** later known as Consumers International, did two pioneering global comparative studies in the 1970s: it examined the marketing and labelling of the drug 'chloramphenicol' (1972) and 'clioquinol' (1975). The results were nothing short of scandalous – double standards, deceit, denial and deliberately taking advantage of countries with weak regulatory authorities; and of the low income countries in general.

The Japan link: The 1979 Kyoto International Conference against Drug-Induced Sufferings was another landmark that linked IOCU to a global network of medical pharmaceuticals and legal specialists.

Later the IOCU 10th Congress in the Hague in 1981 triggered the historic International Conference on Consumer Health and Safety held in April 1983, in Ranzan, Japan, that brought together many allies who combined their strength over the years.

The inspiration of IBFAN: Parallel to these efforts was a global campaign to protect the culture of breastfeeding, which had been murderously undermined by a global infant formula industry. The groups developed a loose but effective global network – with a clear vision and target of do-able things – anytime and anywhere. *The International Baby Food Action Network* (IBFAN) was born in Geneva in October 1979. It provided the model for HAI. The greatness of the network was its simplicity and the fact that diverse partners were able to engage in diverse ways to link and multiply. What was fortuitous was that so many groups involved in the campaign were 'development' and social justice activists who had concerns about the pharmaceutical industry and 'unhealthy' business, in general.[1]

The beginning: The 34th World Health Assembly (WHA), was held in Geneva in May 1981 and representatives from many non-government and activist groups were present including Dato' Anwar Fazal.

At that WHA meeting, the World Health Organisation passed (with one dissenting vote from the USA) the Code of Marketing of Breastmilk Substitutes. That was cause for celebration. As part of the celebration, at the end of this historic WHA meeting from 27-29 May 1981, an International NGO Seminar on Pharmaceuticals was organised and co-sponsored by the International Organisation of Consumer Unions (IOCU) and BUKO Pharma, a German-based health activist group (Bundeskongress Entwicklungspolitischer Aktions-gruppen) in Geneva,. Representatives of NGOs from 26 countries participated and decided to form ***Health Action International*** (HAI), an 'International Antibody' to resist Ill-treatment of consumers by Multinational Drug Companies.

The Consumers International Regional office for Asia and the Pacific (CIROAP) agreed to be the clearing house for HAI. Following the recommendation of Dato' Anwar Fazal, Director of IOCU ROAP 1975 – 1991, and Dr Prem Chandran John, chairman of the ***Asian Community Health Action Network*** (ACHAN), a planning meeting in Penang in 1986 set up ***Action for Rational Drugs in Asia*** (ARDA). IOCU-ROAP and ACHAN would be part of the network in Penang to be known as the ARDA network. The All India Drug Action Network, founded and Coordinated by Dr Mira Shiva became an important partner.

Other network partners were identified and brought in – together with the Poison Centre at the Science University of Malaysia (USM). That Centre became a WHO collaboration centre. In Penang there was a close association between the network and the University Medical Faculty under Vice Chancellor Dzulkifli Abdul Razak (Dzul).

In the late 1980s, Dr Kumaraiah Balasubramaniam (Bala) took up the position as adviser and coordinator of CI-ROAP, and relocated to Penang in Malaysia, having been very active on pharmaceutical issues in UNCTAD and a protégé of the great Dr Seneka Bibile in Sri Lanka.

2001: The change to HAIAP and the move to Sri Lanka

A major achievement of the ARDA network was forging a new level of partnerships between the participating organisations. In 1995 an external evaluation of the ARDA network had been done. The evaluation was positive about the need for the network in Asia and the Pacific regions and ARDA was advised to expand membership and work with more network partners. In 2001 ARDA decided at a meeting held from 18 – 22 Feb 2002, to relocate out of IOCU-ROAP and to set up as an independent NGO based in Colombo, Sri Lanka. For uniformity with the other three HAI centres (Europe, Latin America and Africa) the Asia Pacific office was registered as HAI Asia Pacific with its own Governing Council, and

[1] Many think this code frightened Pharma that a code of Marketing was coming for them too. Result - WHO Ethical Criteria (not as strong as code) and the IFPMA Code which were not as strong as 'Code of Marketing' - well at least we 'saved' the babies KW.

based in Colombo. HAIAP would continue with the campaign issues, rational medicines use and economic matters and take up new issues in the area of poverty, health and traditional medicines.

2010 HAIAP Meeting in Sri Lanka.

In 2010, the last regional meeting of HAIAP before Dr Bala's retirement took place at the Tamarind Tree, Minawangoda, Sri Lanka. At that meeting *Where There Are No Pharmacists* was proudly launched. But also at that meeting we learnt that funding for HAIAP from the Dutch government would not continue. Everyone wanted HAIAP to continue but with no funding there would be major problems. Bala had been in contact with Shila Kaur who had been working with Bala in Penang and she had agreed to coordinate HAIAP from Penang without core funding. She would attempt to find enough employment to support herself and would try to find project grants. So Shila accepted the position as HAIAP coordinator on those terms. Members were very sad to leave Sri Lanka but more than grateful to Shila for allowing us to maintain the HAIAP family. Sadly we lost Dr Bala[2] in April 2011 and Shila[3] in November 2017.

The HAI / HAIAP story is a story of partnerships throughout our regions - scientists and social activists, doctors and health workers, global groups and grassroots effort - that have made what has become a significant force.

The rampant globalisation and misleading marketing within the milieu of a global pandemic are also leading to arousal of public interest groups all over the world to join and strengthen the networks for change to just and equitable health systems.

To all those co-travellers on the HAIAP journey over the last 40 years we say thank you.

Do keep in touch.

[2] http://www.haiasiapacific.org/wp-content/uploads/2014/03/Kumaraiah-Balasubramaniam.pdf

[3] http://www.haiasiapacific.org/wp-content/uploads/2017/12/HAIAPNews2RedDec2017.pdf

Access to affordable new medicines, vaccines and devices:
History, Complex Issues and Advocacy

Beverley Snell

TRIPS = Trade Related Aspects of Intellectual Property Rights

For 10 years after introduction of the Essential Drugs Concepts and recommendation for use of generic drugs the Pharmaceutical Industry negotiated quietly behind the scenes and came up with TRIPS - why?

The WHO and others had been advocating for access to affordable essential drugs, threatening Multi National Company (MNC) sales. Activists including HAIAP Members were highlighting abusive industry practices such as misleading labelling and advertising; and the excessive prices being charged for medicines. International activities were taking place and published books[4] exposed MNC power and unfair practices.

Example of early books on MNC practices affecting access to safe and affordable essential medicines

Ivan Illich: *Medical Nemesis: The Expropriation of Health*. Calder & Boyar 1975

Tom Heller: *Poor health, Rich Profits: Multinational Drug Companies and the Third World.* Spokesman Books. 1977

Charles Medawar, *Insult or injury?: An enquiry into the marketing and advertising of British food and drug products in the Third World.* Social Audit 1979

Joyce Bichler, *DES Daughter: The Joyce Bichler Story*. Avon 1981

Diana Melrose, *Great Health Robbery: Baby Milk and Medicines in Yemen*. Oxfam 1981

Charles Medawar and Barbara Freese. *Drug Diplomacy: Decoding the Conduct of a Multinational Pharmaceutical Company and the Failure of a Western Remedy for the Third World*. Social Audit. 1982

Diana Melrose, *Bitter Pills: Medicines and the Third World Poor*. Oxfam 1982.

Mike Muller, *The Health of Nations*. Faber & Faber 1982

Milton Silverman; Lee PR and Lydecker M. *Prescriptions for Death: The Drugging of The Third World* University of California Press. 1982

An annotated list of 288 publications up to 2011 has been prepared by E-drug and is available on the HAIAP website *

At the same time United Nations Industrial Development Organisation (UNIDO) worked to transfer pharmaceutical technology to developing countries; and India enabled development of strong generic industries.

Dr Zafrullah Chowdhury and colleagues in Bangladesh founded Gonoshasthaya Kendra (GK) and developed a pharmaceutical policy that emphasised access to essential drugs and GK commenced local manufacture.

A strong people's health movement, with links in many cases to Ministries of Health, had developed.

Then came the TRIPS Trade Related Aspects of Intellectual Property Rights introduced by the World Trade Organisation in 1995.

To benefit from trade agreements, all countries in the world needed to become part of the World Trade Organisation by 2005 - except least developed countries (LDCs) who were given a longer time frame to join. The TRIPS 'route' required 'Harmonisation' by 2005 (2016 for LDCs) which meant that all companies would comply with a 20 year patent for new entities and for new indications for old entities.

The patent provision was to 'reduce impediments to trade' and to 'promote technological innovation and transfer to the mutual advantage of producers.

Pre TRIPS, 50 countries did not respect pharmaceutical patents at all. Some countries believed that health products should not be covered by patents. Canada did not respect pharmaceutical patents and had Compulsory Licensing for drugs from 1923 to 1993 with the effect of making generics available at 53.6% of brand name prices.[5] At that time, India did not implement pharmaceutical patents but now a new Indian Patent Act changes everything.[6] Introduction of TRIPS standards delays the introduction of generic versions of ***new*** drugs. Generic versions may not be produced until the patent expires – after 20 years.

TRIPS Flexibilities to cover emergencies

To cover 'emergencies' Articles 30/31 in the TRIPS Agreement spells out flexibilities that allow compulsory licensing to manufacture patented products without permission of the 'rightful owner' during a national emergency.

Other articles include more flexibilities to cover public health need and public use - some safeguards that can be used to mitigate the potential negative effects of TRIPS on access to medicines.

The most important safeguards:

- **Compulsory Licensing and Government Use**
- **Parallel Importation**
- **Bolar' provision**

*http://www.haiasiapacific.org/resources/list-of-books-on-pills

[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3307559/

[6] https://link.springer.com/chapter/10.1007/978-981-13-8102-7_11

These safeguards can only be used when incorporated into ***existing national laws*** so the national health and medicines related legislation must provide in advance for use of TRIPS flexibilities.

A Compulsory License (CL)

- A license granted without permission of the patent holder to manufacture a product; or import the product from a country with a CL to manufacture.

TRIPS allows CL in case of national emergency or extreme urgency, for public non-commercial use.

TRIPS does *not* limit the grounds for issuing a CL but TRIPS *does* specify conditions to be applied to CL applications, including:

- case-by-case decision
- a voluntary license that is agreed in consultation with the patent owner and with a small percentage reimbursement must be attempted first
- the CL agreement must include adequate remuneration to the patent holder
- the CL must be predominantly for provision to the domestic market.

Parallel importation - is importation without the consent of the patent holder, of a patented product marketed either by the patent holder or his licensee at a lower price, from another country.

The 'Bolar' provision allows testing and regulatory approval processes of generic drugs before the patent expires in preparation for local production or import of generic products under a CL - facilitating generic competition.

Government Use is a special case of compulsory licensing for the Government itself - that is for the public sector - making it the easiest procedure to use to access needed products. Medicines produced or accessed under Government Use license cannot be sold commercially but that is not an issue for medicines that are urgently needed for public sector use. All WTO member countries can use the Government Use clause. For example, in 2001 the US government was about to buy generic ciprofloxacin using the Government Use clause to 'stock up' when there was an anthrax scare. [7] However, before the authorisation was issued, Bayer agreed to sell 100 million tablets of ciprofloxacin to the US government at 95 cents each — 54% of its original wholesale price of $1.77. Three other drug manufacturers said that they would supply large quantities of their antibiotics free if the Food and Drug Administration approved their use for the free treatment of anthrax. An anthrax emergency did not occur.

Procedure for seeking a Compulsory License (having ensured there are legislative provisions in place)

Compulsory licenses are needed for both importing and exporting countries. Countries without adequate manufacturing capacity that need to access cheaper generic medicines need to have their own CL to enable them to purchase the cheaper generics from a country with manufacturing capacity and a CL. Countries should first notify WTO (except least-developed countries) and provide details of intended actions.

The WTO needs to be notified of the grant of compulsory license; and measures in place so re-exportation to countries without compulsory licenses can be prevented. Notification is also needed of special labelling, packaging and/or colouring/shaping. The WTO will undertake annual review of the system.

As if the required procedures aren't onerous enough there are additional 'TRIPS-plus' requirements associated with **bilateral/regional trade agreements** between developed and developing countries - demands that countries provide protection for intellectual property rights that go even beyond what is required under TRIPS. There is a need for both health and trade sectors of governments to remain vigilant and aware of trade agreements being considered, and to work together to safeguard access to medicines.

The Doha Declaration At the 4th WTO Ministerial Meeting in Doha in 2001, pressure from activists, International NGOs, and the World Health Assembly convinced delegates that Public Health should take precedence over commercial interests and that TRIPS flexibilities must be made easier to use for accessing affordable essential medicines in developing countries. At the end of the meeting the ***Doha Declaration*** was issued.

The Declaration from the 4th WTO ministerial conference in Doha (Oct-Nov 2001) provided a clear political statement that public health concerns must override commercial interests and 'a road map to key flexibilities in TRIPS' was prepared leaving countries free to determine what is a national emergency'. The Declaration stated:

- Where patent medicines are beyond the reach of people who need them, governments can override patents without negotiations with companies and without threat of retribution.
- Countries can make their own rules about parallel imports.
- Procedures for issuing a compulsory license must become easier, faster.

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1121539/

- Least developed countries were granted 10 year extension - TRIPS compliance would be necessary at the earliest by 2016 instead of 2006.

Paragraph 6 of the Doha Declaration recognises that it is not clear how countries with insufficient or no manufacturing capacity can make effective use of compulsory licensing, and instructs the WTO's TRIPS Council to 'find an expeditious solution' to this problem.

What is a patent?

Patent can cover the actual product, its formulation, method of manufacture (process) and – in some cases - indication. In some countries 'use' is patented. In other countries the word 'indication' is used. One example of the patenting of a *new* use for an old drug is AZT (zidovudine) invented in 1964 for cancer but patented for HIV in 1986. Another example is pyrimethamine – invented in 1953 but remarketed for HIV in 2015 at around 5000 times the price.

Generics must not be confused with counterfeit medicines !

What are counterfeit pharmaceutical products?

- Counterfeit products are illegal imitations of legitimate products that are meant to deceive buyers.
- They demonstrate several criteria:
- They are deliberately and fraudulently mislabeled with respect to identity and/or source
- They can be branded and generic
- They can include products:
  - With correct ingredient(s)
  - With wrong ingredient(s)
  - Without active ingredient(s)
  - With insufficient quantity of active ingredient(s)
  - Or with fake packaging.
- Worse – products may contain other ingredients that are harmful. For example in 2001, diethylene glycol as an excipient in a paracetamol preparation led to some thousands of deaths in China; in the USA, fake heparin may have led to more than 60 deaths in 2008. *

*https://www.nytimes.com/2007/06/17/health/17poison.html

New Patent of an old drug: **Pyrimethamine** came into use in 1953 for treatment of malaria and other parasites - available as a generic for prices ranging from US$0.04 to US$0.10 each. When in 2015 pyrimethamine was found to be useful as part of management of HIV infections, Turing Pharmaceuticals acquired the US marketing rights for the product to be sold as Daraprim and the price was increased to $750 per tablet. Martin Shkreli, CEO of Turing defended the price hike.

In 2016, a group of high school students in Sydney prepared pyrimethamine as an illustration that the synthesis is comparatively easy and the price-hike unjustifiable. The student team produced 3.7 g for US$20, which would have been worth between US$35,000 and US$110,000 in the United States at the time. The students' work was featured in The Guardian, Time magazine, on ABC Australia, the BBC, and CNN.

Pyrimethamine was approved as a generic in the United States in February 2020.

In India, many manufacturers sell pyrimethamine tablets for malaria and parasites, and multiple combinations of generic pyrimethamine are available for a price ranging from US$0.04 to US$0.10 each (3–7 rupees). In Brazil, the drug is available for R$0.07 a pill, or about US$0.02.

In 2018, Shkreli was sentenced to 7 years in a US Federal prison on charges of conspiracy to commit fraud.

https://www.bbc.com/news/world-us-canada-40833097

A generic drug?

A copy of a product that was originally patented under a trade name; old drugs are freely manufactured as generics, eg paracetamol. Generic drugs must be subject to exactly the same quality control specifications as original patented products to comply with registration requirements but not all countries have facilities to ensure those standards. Generic medicines are legitimate copies of patented (branded) pharmaceuticals. They can be produced after expiry of patent protection or under the flexibilities of Intellectual Property law.

A generic is a legitimate quality-assured copy of a medicine – a counterfeit is an illegal faked copy intended to deceive buyers.

Several countries have introduced legislation to control counterfeits but lack of awareness of the difference has meant that in some cases the laws have also affected the import of legitimate generic medicines. In 2009[8] [1] a Customs' incorrect interpretation led to blocking transit of good generics through Schipol airport.[9]

8. Court ruling in Kenya a victory for access to medicines http://www.essentialdrugs.org/edrug/archive/201004/msg00036.php

9. http://www.essentialdrugs.org/edrug/archive/201004/msg00036.php

HIV tested TRIPS flexibilities

The emergence of HIV from the early 1980s and the need for access to new drugs severely tested countries' capacity to use the flexibilities of the TRIPS agreement.

- *An HIV +ve activist in the 80s said .. 'When I started campaigning for the rights of people to access appropriate drugs for treatment of HIV, I had no idea I would need to have a complete knowledge of international trade law'.* [10]

Examples of efforts to use CLs

Thailand didanosine (ddl)

In 1999, Thailand's Government Pharmaceutical Organisation (GPO) asked for permission to acquire CL to manufacture didanosine (ddl) (for reasonable royalty) under Article 51 of their Patents Law. Legislative provisions were in place. The GPO had the capacity to manufacture meeting all criteria for Good Manufacturing Practice (GMP). The patent had been held by Bristol Myers Squibb (BMS) since 1992.

USA, under a 'Free Trade Agreement' threatened trade sanctions if the plan went ahead. Although legally the CL could be applied certain Thai politicians feared trade sanctions.

A group of 15 public health activists supported by the Thai Law Society agreed to help and after a campaign lasting until March 2004 BMS gave up and generic didanosine was produced by the GPO.

South Africa, fluconazole

South Africa, 2000: fluconazole was needed for opportunistic fungal infections associated with HIV infection. South Africa's Patent Law recognised the Pfizer patented version of fluconazole that cost $US4.15/day for patients as opposed to $US 0.29/day for the generic product that was available from India. Zackie Achmat, HIV positve member of the South African *Treatment Action Campaign* (TAC) bought fluconazole in India for use by South African HIV positive patients suffering opportunistic fungal infections and was imprisoned on his return to South Africa for breach of Patent Law.

Médecines sans Frontières (MSF) and the TAC campaigned for Pfizer to reduce the price to 60c/day or allow a voluntary licence. Pfizer refused and offered to donate the drug as part of their own clinical trial with a group of selected doctors. There were onerous reporting and training requirements for the selected doctors and the trial restricted use to cryptococcal meningitis (not for oral thrush, or other life-threatening candidiasis, etc) and there was a time limit imposed on donation. Finally, under continued pressure, generic fluconazole import was allowed for pilot programs, for example in Khayelitsha, a poor township near Capetown, so long as it was bought by MSF. The patent expired in January 2004 allowing generic production.

Costs of developing new medicine, vaccines and devices

Pharmaceutical manufacturing companies claim that the enormous cost of research and development (R&D) of new entities justifies the very high prices of newly developed entities; it is necessary to recoup the R&D costs in order to continue to develop new products. However, the true costs of R&D are rarely - if ever- declared and they are often subsidised by governments, universities and philanthropic organisations

On 20 June, 2020 it was announced that the pledges to the COVID-19 Global Response amounted to US$15.9 billion. Forty governments had pledged to ensure universal access to corona virus medicines and vaccines and to help rebuild communities that had been hit hardest by the pandemic in a fair and just way.[11] Included were commitments to the production capacity for **over 250 million vaccine doses** for middle and lower income countries (LMICs).

According to Medicines Law and Policy [12] the commitment of vaccine manufacturing companies is to the countries who made advance purchasing agreements (APAs) - not commitment to LMICs. Any vaccines left over from satisfying those APA needs might be available to LMICs.

What has happened to the pledge for equity?

And the proclamation that 'no one is safe until all are safe'?

The vaccine manufacturers demand that no rich countries will help LMICs by providing free or cheaper vaccines.

So it is more important than ever that the LMICs must have access to the TRIPS flexibilities easily. Without

10. http://www.tac.org.za/home.htm

11 https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1213

12 https://medicineslawandpolicy.org/2021/01/the-european-commission-says-covid-19-vaccines-should-be-global-public-goods-but-do-their-agreements-with-pharma-reflect-this/

a WAIVER easy use of TRIPS flexibilities is not possible.

Although the World Health Assembly and the Doha Ministerial meeting declared public health takes priority over commercial concerns ***TRIPS hurdles must be jumped in order to use the flexibilities.***

- Many LMICs that did not even have a domestic patent scheme prior to the TRIPS Agreement are forced to undertake a dramatic administrative and legislative transformation before taking advantage of the TRIPS flexibilities under Articles 30/31. Not only do many of the national laws have to change to adopt the provisions of the agreement, but an elaborate database of patents will need to be established.
- Lack of awareness of flexibilities and poor coordination between ministries or lack of awareness of implications of actions, eg trade agreements, lead to confusion and can lead to inability to fulfil the requirements for an application.
- There can be a 'chill factor' - governments may be scared to use their rights because of real or perceived threats from powerful countries or pharmaceutical companies.
- Myths and misinformation are spread concerning the rights of governments to use the TRIPS flexibilities.

Therefore, we call on all WTO members to urgently support the ***waiver*** proposed by India, South Africa and other countries that will facilitate the generic manufacture of approved quality vaccines by countries with manufacturing capacity and access from those countries by others without the capacity.

Why is advocacy needed?

- To support peoples' rights - solidarity
- To counter misinformation about what is possible and what is legal
- To clear up legal uncertainty of rights under TRIPS
- To counter efforts to weaken provisions of the Doha agreement - advocacy needs to be directed at delegates at regional meetings and 'ministerials'
- To counter pressure on countries from vested interests eg MNCs and the US and other governments
- To address poor coordination between ministries or lack of awareness of implications of actions, eg trade agreements
- 'chill factor' - to support governments who are frightened to use their rights because of perceived threats
- To counter myths and misinformation

In October 2020, India and South Africa had asked the World Trade Organisation to waive the protections on a temporary basis so that COVID-19 vaccines and equipment could be made more cheaply at greater scale. Australia joined Britain, the US and the EU in opposing the move, arguing that existing licensing rules would be sufficient to meet the needs of LMICs – an assertion that has been shown to be untrue.

'Whoever Finds a Vaccine Must Share It'

Strengthening Human Rights and Transparency

Around COVID-19 Vaccines
SUMMARY from Human Rights Watch http://www.hrw.org

The COVID-19 pandemic is among the gravest global health and economic crises in history. By mid-October 2020, it had taken the lives of more than a million and infected at least another 38 million, leaving many of them severely ill. Its social and economic consequences have been widespread and devastating. World over, people have been pinning their hopes on potential COVID-19 vaccines. The race to develop and distribute COVID-19 vaccines has made headlines nearly every day since the World Health Organization (WHO) first described COVID-19 as a pandemic in March 2020.

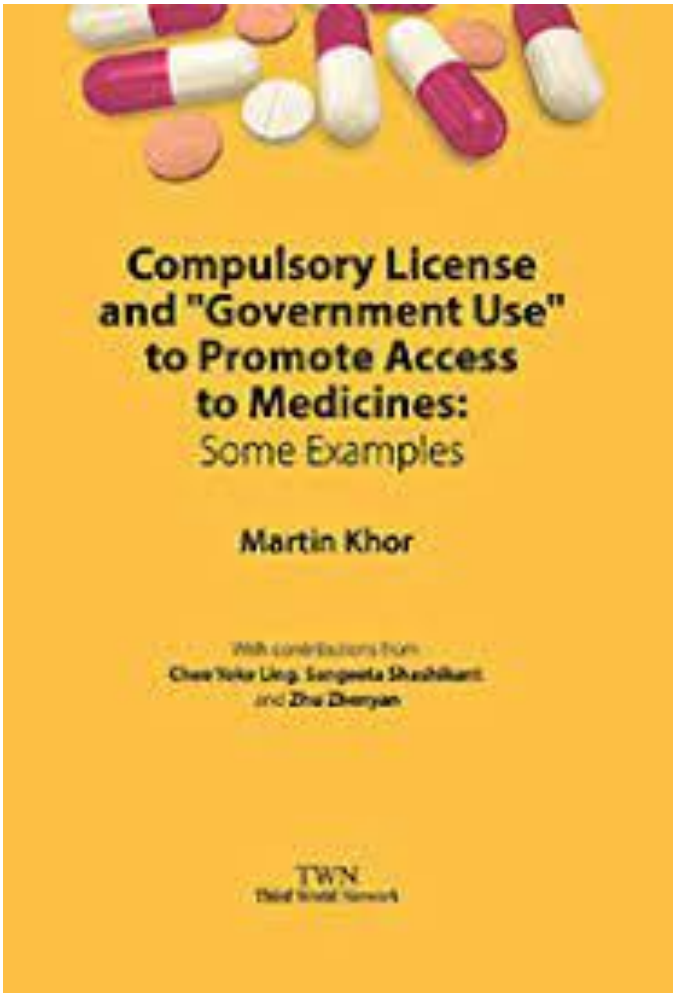
Currently there are around 170 vaccines on trial or distributed by companies or research institutes headquartered in China, Germany, Russia, the United Kingdom, and the United States. They fall into four categories. [13]

Universal and equitable access to a safe and effective COVID-19 vaccine is critical to ending the pandemic, or if no vaccine provides absolute immunity, preventing severe illness and death while protecting livelihoods and allowing battered economies to recover from the consequences of the pandemic. Governments—especially high-income countries that can afford to do so—are using public money to fund COVID-19 vaccines on an unprecedented scale. Commitments to meet human rights obligations and transparency have been largely absent. Rich governments that can afford to do so are negotiating opaque bilateral deals with pharmaceutical companies or other entities, often reserving future doses of vaccines largely for their own exclusive use. Secret deal-making and hoarding future vaccines in climate where vaccines are widely projected to be in scarce supply—an approach often described as 'vaccine nationalism'—have dealt massive blows to any global vision for universal and equitable access to an affordable vaccine, leaving people from LMICs to pick through whatever is left after rich countries have served themselves. As Fatima Hassan, a South African human

[13] https://www.gavi.org/vaccineswork/there-are-four-types-covid-19-vaccines-heres-how-they-work

rights lawyer and intellectual property (IP) rights expert said, 'How vaccines are distributed will expose the divides by race, class, and economic power.'

Human Rights Watch has carried out extensive research examining the rights implications surrounding COVID-19 vaccine availability and affordability.



Available from TWN

https://www.twn.my/title2/books/CompulsoryLicense.htm

The Doha Declaration on TRIPS and Public Health that was adopted by the WTO (World Trade Organization) Ministerial Conference of 2001 reaffirmed the rights of Members to issue a compulsory license when negotiations for a reasonable price or a voluntary license to import or manufacture a patented product from the patent holder fail.

This book describes the experiences of a number of developing countries in exercising their rights to use compulsory licensing, especially a license for 'government use'. This is a form of compulsory license that is issued to obtain generic medicines for use in public hospitals and clinics, through imports or domestic production.

Copies of the actual compulsory licenses of the developing countries are included for reference.

1. National Public Health Measures that are TRIPS-Consistent: Importing the Drug, Local Manufacture, Export, Including to Countries with Inadequate Manufacturing Capacity.

2. Use of TRIPS Flexibilities: in a range of countries

3. Implications of Bilateral FTAs on Implementation of TRIPS Flexibilities Regarding Public Health:

The world's poorest countries are at India's mercy for vaccines. It's unsustainable [14]

[Ed: India must have sovereignty over its own vaccine production – should not remain answerable to AstraZeneca]

Achal Prabhala and Leena Menghaney

Achal Prabhala is the coordinator of the AccessIBSA project, which campaigns for access to medicines in India, Brazil and South Africa; Leena Menghaney is an Indian lawyer who has worked for two decades on pharmaceutical law and policy. She is Manager of MSF's Access Campaign in India.

Fri 2 April 2021 F

This is what happens when a third of humanity depends on one manufacturer for COVID jabs. We need to waive patents now.

As the UK's vaccination program was knocked of course due to a delay in receiving five million doses of the AstraZeneca vaccine from India, a far more chilling reality was unfolding: about a third of all humanity, living in the poorest countries, found out that they will get almost no coronavirus vaccines in the near future because of India's urgent need to vaccinate its own massive population.

It's somewhat rich for figures in Britain to accuse India of vaccine nationalism. That the UK, which has vaccinated nearly 50% of its adults with at least one dose, should demand vaccines from India, which has only vaccinated 3% of its people so far, is immoral. That the UK has already received several million doses from India, alongside other rich countries such as Saudi Arabia and Canada, is a travesty.

The billions of AstraZeneca doses being produced by the Serum Institute in India are not for rich countries – and, in fact, not even for India alone: they are for all 92 of the poorest countries in the world.

How did we get here? Exactly one year ago, researchers at Oxford University's Jenner Institute, frontrunners in the race to develop a coronavirus vaccine, stated that they intended to allow any manufacturer, anywhere, the rights to their jab. One of the early licences they signed was with the Serum Institute, the world's largest vaccine

[14] https://www.theguardian.com/commentisfree/2021/apr/02/india-in-charge-of-developing-world-covid-vaccine-supply-unsustainable?fbclid=IwAR2QUFzikJ_al5npOpGvH_kcDc5to3iPf4lyZdS0si_CVLE6NBiVClEXA14

manufacturer. One month later, acting on advice from the Gates Foundation, Oxford changed course and signed over exclusive rights to AstraZeneca, a UK-based multinational pharmaceutical group.

AstraZeneca and Serum signed a new deal. Serum would produce vaccines for all poor countries eligible for assistance by GAVI, the Vaccines Alliance – an organisation backed by rich countries' governments and the Gates Foundation. These 92 nations together counted for half the world – or nearly four billion people. India's fair share of these vaccines, by population, should have been 35%. However, there was an unwritten arrangement that Serum would earmark 50% of its supply for domestic use and 50% for export.

The deal included a clause that allowed AstraZeneca to approve exports to countries not listed in the agreement. Some countries which asked for emergency vaccine shipments from Serum, including South Africa and Brazil, were justified: they had nothing else. Rich countries like the UK and Canada, however, which had bought up more doses than required to vaccinate their people, to the detriment of everyone else, had no moral right to dip into a pool of vaccines designated for poor countries.

Paradoxically, when South Africa and India asked the World Trade Organization to temporarily waive patents and other pharmaceutical monopolies so that vaccines could be manufactured more widely to prevent shortfalls in supply, among the first countries to object were the UK, Canada and Brazil. They were the very governments that would later be asking India to solve their own shortfalls in supply.

The deal did not include restrictions on what price Serum could charge, despite AstraZeneca's pledge to sell its vaccine for 'for no profit during the pandemic' which led to Uganda, which is among the poorest countries on earth, paying three times more than Europe for the same vaccine. (An AstraZeneca spokesperson told Politico that the 'price of the vaccine will differ due to a number of factors, including the cost of manufacturing – which varies depending on the geographic region – and volumes requested by the countries'.)

As it became clear that the western pharmaceutical industry could barely supply the west, let alone anywhere else, many countries turned to Chinese and Russian vaccines. Meanwhile, the Covax Faciity – the Gavi-backed outfit that actually procures vaccines for poor countries – stuck to its guns and made deals exclusively with western vaccine manufacturers. From those deals, the AstraZeneca vaccine is now the only viable candidate it has. The bulk of the supply of this vaccine comes from Serum, and a small quantity from SK Bioscience in South Korea. As a result, a third of all humanity is now largely dependent on supplies of one vaccine from one company in India.

Cue the Indian government's involvement. Unlike western governments, which poured billions into the research and development of vaccines, there is no evidence that the Indian government has provided a cent in research and development funding to the Serum Institute. The Indian government then commandeered approval of every single Covax shipment sent out from Serum – even, according to one well-placed source within the institute, directing how many doses would be sent and when.

Last month, faced with a surge in infections, the Indian government announced an expansion of its domestic vaccination program to include 345 million people, and halted all exports of vaccines. About 60 million vaccine doses have already been dispensed, and the government needs another 630 million to cover everyone in this phase alone.

One other vaccine is approved for use – Bharat Biotech's Covaxin – but it is being produced and utilised in smaller quantities. As more vaccines are approved, the pressure on Serum might decrease. For now, however, the bulk of India's vaccination goals will be met by just one supplier, which faces the impossible choice of either letting down the other 91 countries depending on it, or offending its own government.

The consequences are devastating. To date, 28 million Covax Facility doses have been produced by Serum for the developing world – 10 million of which went to India. The second largest shipment went to Nigeria, which received 4 million doses, or enough to cover only 2% of its population. Given the new Indian government order of 100 million doses, further supplies to countries like Nigeria may be delayed until July. And given the Indian government's need of 500 million more vaccine doses in the short run, that date could surely be pushed out even further.

This colossal mess was entirely predictable. Oxford University should have stuck to its plans of allowing anyone, anywhere, to make its vaccine. AstraZeneca and Covax should have licensed as many manufacturers in as many countries as they could to make enough vaccines for the world. The Indian government should have never been effectively put in charge of the wellbeing of every poor country on the planet.

For years, India has been called the pharmacy of the developing world'. It's time to rethink that title. We will need many more pharmacies in many more countries to survive this pandemic.

WTO DG's vaccine event marked by sharply differing perspectives

By D. Ravi Kanth TWN April 15 [15]

[Ed: This Report describes the deliberations at the WTO meeting held on April 14 where complete lack of progress towards equitable access to COVID-19 vaccines was demonstrated.]

The WTO director-general Ms Ngozi Okonjo-Iweala's much touted meeting on addressing 'equitable distribution of COVID-19 vaccines' brought sharply differing perspectives to the fore on various issues, including the role of IPRs and the need to finalize a decision on the temporary TRIPS waiver in ramping up global production of vaccines for combating the worsening pandemic that has claimed more than 2.9 million lives.

At the more than five-hour virtual meeting chaired by Ms Okonjo-Iweala on 14 April, trade ministers from India and South Africa as well as the World Health Organization Director-General called for the temporary TRIPS waiver in ramping up production of diagnostics, therapeutics and vaccines across countries to prevent and treat the COVID-19 pandemic.

Despite holding meetings with labour unions, advocacy groups and pharmaceutical lobbies on 13 April, the US Trade Representative (USTR) Ambassador Katherine Tai remained silent on the TRIPS waiver at the meeting convened by the WTO DG.

April 15 [16]

Support for US to waive patents

Data for Progress and the Progressive International showing a large majority of US support for Joe Biden to waive patents on COVID-19 vaccines at the World Trade Organization — 60% in favour to just 28% against, with over 72% of Democrat support. Responding to the poll, Senator Bernie Sanders said:
'I strongly believe that the United States should be leading the global effort to end the coronavirus pandemic. Supporting a temporary WTO waiver, which would enable the transfer of vaccine technologies to poorer countries, is a good way to do that. This virus does not respect borders. The bottom line is, the faster we help vaccinate the global population, the safer we will all be. That should be our number one priority, not maximizing the profits of pharmaceutical companies and their shareholders'.

Separately, over 170 former heads of state and government as well as Nobel Laureates on 14 April urged US President Joseph Biden to support the proposed TRIPS waiver. (See Box next page.)

However, the Republican members in the House Ways and Means Committee fiercely opposed the TRIPS waiver and wrote a letter to President Biden to oppose the waiver at the WTO on 14 April.

The EU, however, spoke about the Ottawa Group's trade and health initiative, which has few supporters at the WTO, Brussels opposed the TRIPS waiver.

The meeting also witnessed differences in perspectives for manufacturing vaccines between Pfizer and Moderna on the one side, and Bharat Biotech from India, Aspen from South Africa, and Incepta Pharmaceuticals from Bangladesh, on the other.

Pfizer and Moderna apparently ruled out any prospect of sharing their mRNA technology-based vaccines with the vaccine firms in developing countries on grounds that they are far too complex and require more than 100 raw materials, **see Box on Page 20**.

The representatives of these two Northern-based companies, which were bolstered by billions of dollars of public funds for developing their vaccines, maintained that they cannot guarantee safety in the production of vaccines in developing countries.

But vaccine companies from the Global South, particularly Bharat Biotech from India and Aspen from South Africa, pushed back against such hyperbolic claims.

Dr Sai Prasad of Bharat Biotech said his company is pursuing an mRNA vaccine along with several companies, arguing that if companies tend to look inside the box, there may not be any solutions.

But if vaccine companies are able to look out of the box, there are plenty of solutions, suggesting that there are pharmaceutical companies in Bangladesh, Pakistan and Brazil which can produce complex vaccines if requisite technology-transfer is provided under relaxed IPR conditions, said people familiar with the development.

In her concluding statement at the meeting Ms Okonjo-Iweala acknowledged that there are differences among participants 'on issues concerning the future shape of vaccine supply chains, on the appropriate role of intellectual property protections, on issues of vaccine contract transparency – which was pointed to by many as an important factor in appropriate pricing and distribution and a critical part of access and equity.'

Participants said Ms Okonjo-Iweala spoke about the TRIPS waiver in a very positive way in her opening statement, but she went back to her original 'third way' approach in her concluding remarks.

It was also reported that the TRIPS Council chair Ambassador Dagfinn Sorli from Norway suggested at the

[15] https://www.twn.my/title2/wto.info/2021/ti210407.htm

[16] https://progressive.international/wire/2021-04-15-large-majority-of-us-voters-support-patent-waiver-on-covid-19-vaccines/en

meeting that no clear answers were provided about how certain provisions of the TRIPS Agreement could constitute a barrier, in what seemed to be an incorrect statement.

In sharp contrast to Ambassador Sorli's statement, the former TRIPS Council Chair Ambassador Xolelwa Mlumbi- Peter from South Africa suggested that the time for questions centering on the IPR barriers is over and it is now time for moving rapidly to text-based negotiations so as to arrive at a balanced solution as part of the WTO's contribution to the TRIPS waiver.

Significantly, the WHO Director-General Dr Tedros Adhanom Ghebreyesus supported the TRIPS waiver at the meeting, while the International Monetary Fund's Managing Director Ms Kristalina Georgieva pledged considerable support for ramping-up production of vaccines through the proposed creation of hundreds of billions of dollars of Special Drawing Rights.

Also, the head of the World Bank's International Finance Corporation Mr Makhtar Diop said that special funds are being directed to increasing the capacity for producing new vaccines in Africa.

In short, the whole meeting looked like a very shallow conference and also revealed differences in approaches to vaccine equity and ramping-up of production almost along North-South lines.

THE WHO DG

In his strong statement issued at the meeting, the WHO DG Dr Tedros Adhanom Ghebreyesus said the approval and rollout of safe and effective vaccines against COVID-19 were creditable and a stunning scientific development in a matter of one year.

He called for scaling-up production of vaccines, suggesting that governments and pharmaceutical companies need to 'go beyond the traditional modus operandi to provide sustainable and effective solutions to address this extraordinary crisis.'

Dr Tedros suggested that 'the current company-controlled production sharing agreements are not coming close to meeting the overwhelming public health and socio-economic needs for effective, affordable and equitable access to vaccines, as well as therapeutics and other critical health technologies.'

He called for exploring 'every option for increasing production, including voluntary licenses, technology pools, the use of TRIPS flexibilities and the waiver of certain intellectual property provisions.'

He outlined three ways to overcome 'the obstacles' faced by members. They include:

1. Companies must share know-how, intellectual property and data with other qualified vaccine manufacturers, including in low-and middle-income countries, as COVAX and COVID-19 Technology Access Pool or C-TAP have failed to deliver results;

2. Countries must strengthen their regulatory capacity; and

3. Countries must invest in local vaccine manufacturing.

He reminded the participants at the meeting that 'responding to this unprecedented crisis means thinking and doing things differently.'

Ultimately, said Dr Tedros, 'putting aside the old barriers and the limitations of short-term self-interest is the only way to build the safer, healthier and fairer world we all want.'

The European Union's Trade Commissioner Mr Valdis Dombrovskis spoke in favour of voluntary licenses and using the existing TRIPS flexibilities such as compulsory licenses among others.

He also called for 'ensuring transparency and effective monitoring of any temporary export restriction, as proposed by the Ottawa Group.'

India and South Africa

In sharp contrast, the trade ministers of India and South Africa pressed for the TRIPS waiver that seeks to suspend several provisions in the TRIPS Agreement relating to copyrights, industrial designs, patents, and protection of undisclosed information to ramp up global production of diagnostics, therapeutics and vaccines in order to combat the COVID-19 pandemic.

India said that the shortfalls in vaccines is due to limited licensing agreements, emphasizing that the TRIPS waiver can address issues concerning prevention, treatment, and containment of COVID-19.

The Indian minister Mr Piyush Goyal also assured the participants that the proposed waiver is not intended to take away the protection offered to pharmaceutical companies.

The waiver is only meant for COVID-19 vaccines, associated medicines and a cure, India said, arguing that although this meeting is focused on the so-called 'third way', it is important to engage all potential manufacturers on a transparent framework, according to participants familiar with the proceedings.

Ms Okonjo-Iweala underscored the need for a 'business unusual' approach to solve problems concerning issues relating to scaling-up of production, particularly in developed and developing countries.

Ms Okonjo-Iweala said that during the meeting, roughly 50 speakers took the floor, suggesting that it 'would serve as the basis for continued dialogue aimed at delivering results in terms of increased vaccine production volumes in the short-term as well as longer-term investments in vaccine production and enhancing the trading system's contribution to pandemic preparedness.'

2021 April 7 World Health Day

Philippines

2021 Year of the Health and Care Workers[17]

2021 has been designated as the International Year of Health and Care Workers (YHCW) in appreciation and gratitude for their unwavering dedication in the fight against the COVID-19 pandemic. WHO is launching a year-long campaign, under the theme – **Protect. Invest. Together.** It highlights the urgent need to invest in health workers for shared dividends in health, jobs, economic opportunity and equity.

This year, we are calling on your support and action to ensure that our health and care workforces are supported, protected, motivated and equipped to deliver safe health care at all times, not only during COVID-19. Today, we ask that you to add your voice to those calling for additional investments in health and care workers.

Campaign objectives

- Ensure the world's health and care workers are prioritised for the COVID-19 vaccine in the first 100 days of 2021.
- Recognize and commemorate all health and care workers who have lost their lives during the pandemic.
- Mobilize commitments from Member States, International Financing Institutions, bilateral and philanthropic partners to protect and invest in health and care workers to accelerate the attainment of the SDGs and COVID-19 recovery.
- Engage Member States and all relevant stakeholders in dialogue on a care compact to protect health and care workers' rights, decent work and practice environments.
- Bring together communities, influencers, political and social support in solidarity, advocacy and care for health and care workers.

Key messages

The campaign highlights the urgent need to invest in health workers for shared dividends in health, jobs, economic opportunity and equity. This means ensuring appropriate protection and conditions of work. It calls for additional investments in health and care workers' education and employment. It means a shared vision for investing in people as the foundation of Health for All. Together the global community has the opportunity to realize this vision.

- Health and care workers have protected the world during COVID-19: We have a moral obligation to protect them.
- Health workers delivering new COVID-19 health care innovations and vaccines should have the requisite support and enabling work environment. Vaccinating health and care workers first is the right thing to do and the smart thing to do.
- Health and care workers have protected the world during COVID-19: We have a moral obligation to protect them.
- Health workers delivering new COVID-19 health care innovations and vaccines should have the requisite support and enabling work environment. Vaccinating health and care workers first is the right thing to do and the smart thing to do.

Invest in the people who invest in us

The world is facing a global shortage of health workers. We must invest in education, jobs and decent work to protect the world from disease and achieve universal health coverage.

Globally, 70% of the health and social workforce are women. Nurses and midwives represent a large portion of this. We need to invest in gender equity.

Together, we can make it happen

We all have a role to play to ensure that our health and care workforces are supported, protected, motivated and equipped to deliver safe health care at all times, not only during COVID-19.

[17] https://www.who.int/campaigns/annual-theme/year-of-health-and-care-workers-2021

Feature: Public health policies and health-care workers' response to the COVID-19 pandemic, Thailand

[The Bulletin of the WHO highlighted the important role of health workers in Thailand's response to COVID-19. This article is re-produced in full. The authors are congratulated for their extremely comprehensive and useful account of the Thai response to the pandemic. Ed.}

For references see Bull World Health Organ 2021;99:312–318
https://www.who.int/bulletin/volumes/99/4/20-275818.pdf?ua=1
Natthaprang Nittayasoot, Rapeepong Suphanchaimat, Chawetsan Namwat, Patcharaporn Dejburuma & Viroj Tangcharoensathien

Introduction

Wuhan Municipal Health Commission, China, reported a cluster of cases of pneumonia of unknown aetiology, later named coronavirus disease 2019 (COVID-19), on 31 December 2019.1 In response to this threat, the Thailand Ministry of Public Health set up an Emergency Operations Centre on 4 January 2020 to provide daily technical support and advice to the government, was reported in Thailand on 13 January 2020. Epidemiological evidence shows that the index cases were all diagnosed in non-Thai travellers who entered Thailand before international travel restrictions were enforced. These initial cases resulted in the transmission of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) within communities, and the number of new cases peaked in March 2020. Early transmission of the virus was boosted by three clusters of super-spreaders linked to a boxing stadium and to night clubs in Bangkok, and to Muslim pilgrims returning to a few southern provinces from neighbouring countries.

The Thai government established the Centre for COVID-19 Situation Administration, chaired by the Prime Minister, on 12 March 2020 to harmonize and synergize the government response to the pandemic. By May 2020, the government had achieved containment of the virus through public health and social measures. No local transmission was reported from 25 May until several Thai workers illegally crossed the border into Thailand from Myanmar on 7 November 2020.

Despite being the first country outside China to report a positive case of COVID-19, the subsequent number of cases and deaths has been much lower in Thailand than in many other countries. As of 7 January 2021, the number of confirmed COVID-19-positive cases in Thailand was 9636 (138 cases per million population) and the number of deaths caused by the virus was 67 (1 death per million population; case fatality: 0.7%). In comparison, the three most-affected countries at that same date were: the United States of America, with 22.1 million cases and 374,133 deaths; India, with 10.4 million cases and 150,606 deaths; and Brazil, with 8.0 million cases and 200,498 deaths. We review the government policies that enabled early containment to be achieved and that enhanced the capacity of health-care workers to provide an effective response to the pandemic.

Public health workforce [18]

Thailand's successful implementation of universal health coverage (UHC), which began in 2002, demonstrates the value of long-term investment in health systems and primary health care. To accommodate the rapid increase in service utilization required for the implementation of UHC, the Thai government more than doubled the number of qualified nurses and midwives from 84,683 (13.2 per 10,000 population) to 191,575 (27.6 per 10,000 population; 94.8% women) between 2002 and 2018.

[18] https://www.who.int/thailand/news/detail/14-10-2020-Thailand-IAR-COVID19

During the same period, the government implemented policies to almost treble the number of qualified medical doctors from 18,947 (3.0 per 10,000 population) to 55,890 (8.1 per 10,000 population; 44.7% women). However, despite significant progress, the combined population density of doctors, nurses and midwives in 2018 (35.7 per 10.000 population) was still lower than the sustainable development goal (SDG) target 3.c of 44.5 per 10.000 population; efforts to achieve the SDG target health workforce density are ongoing.

To address the previously uneven geographical distribution of health-care workers, the government applied multiple interventions such as: increased training capacity; mandatory (since 1972) rural service by graduate doctors, nurses, pharmacists and dentists; the recruitment of health students from rural backgrounds; a training curriculum that included rural health problems; and financial and non-financial incentives such as social recognition. These interventions, combined with the application of task shifting (the process of delegation of certain tasks, where appropriate, to less-specialized health workers, e.g. nurse practitioners, dental nurses and pharmacy assistants), mean that the geographical distribution of the health workforce has gradually become more equitable.

Thailand is self-reliant in health-care workforce training, both under- and post-graduate, and all health-care workers are qualified to a high standard. Quality is ensured through the national and continual assessment of all cadres of health-care workers; professional medical councils award the relevant qualifications (licenses), and licenses are maintained by the mandatory completion of a sufficient volume of continued professional education within every five-year period.

Public health function

Although there is no global consensus on the exact nature of public health, a few key functions identified by existing public health frameworks include: surveillance, governance and financing, health promotion, health protection and legislation, research and human resources. Public health in Thailand is focused on surveillance, prevention and control, and is fully supported by laboratory and human resources. This definition of public health has been fully integrated at the primary health-care level; district hospitals and health centres provide first-contact services to the entire population.

Disease surveillance has been a function of public health since the inception of the Thai Epidemiology Division in 1970. The first Surveillance and Rapid Response Team was established in 2004, expanding to become a national network of epidemiologists, public health officers and nurses. The teams are responsible for surveillance, outbreak investigations and containment of infectious diseases such as dengue, acute flaccid paralysis, measles, the Zika virus and food poisoning; a total of 87 notifiable diseases were reported in the Weekly Epidemiological Surveillance Report in 2020. This resilience facilitates the capacity to respond to a large public health emergency or pandemic, for example, the avian influenza pandemic in 2004 and the Middle East respiratory syndrome coronavirus in 2015. The Surveillance and Rapid Response Teams have been the main contributors to public health function since the beginning of the COVID-19 pandemic; in 2020, Thailand had around 1000 such teams distributed across the public health ministry, the provincial health offices and all district hospitals.

Further, in recognizing the interaction between humans, animals and wildlife, as well as the need for collaboration between medical doctors, veterinarians working with domestic animals and wildlife, and pharmacists, Thailand launched its 3-year field epidemiology training programme in 1980. The World Health Organization

recommends an optimal workforce density of one trained field epidemiologist or equivalent per 200 000 population. Although there are only 183 trained field epidemiologists, equivalent to 0.55 per 200,000 population, in Thailand,

the shortfall is being met by on-the-job training delivered to public health officers and nurses.

COVID-19 containment

The successful containment of the virus is essential to minimize the additional burden faced by hospitals, prevent health facilities from becoming overwhelmed and sustain the provision of other essential health services. From January 2020 the Thai government implemented several public health interventions to contain the virus, including detection of index cases through laboratory testing and a test-and-trace system to identify all high-risk (i.e. those who have experienced direct contact with respiratory secretions from a COVID-19-positive case) and low-risk contacts. Because voluntary self-isolation at home is not considered to be effective in interrupting transmission, 14-day quarantine at local (i.e. public dormitories or re-purposed sports amenities for Thai citizens in the provinces) or state (i.e. mostly hotels affiliated to hospitals for tests and referrals, for both Thai and non-Thai international travellers) facilities is mandatory for all cases as well as high-risk contacts.

The government mobilized health-care workers, mostly nurses and public health officers, to support the collection of nasal swabs from all Thai and non-Thai travellers at points of entry (air, land and sea ports) for laboratory analysis, as well as history-taking for the test-and-trace system. Workers were also mobilized to manage, supervise and provide services to contacts of cases at the 14-day quarantine sites. These services included daily clinical monitoring, specimen collection for laboratory testing (at days 3–5 and 11–13) and referral of all positive cases to hospital according to the national protocol.

Contact tracing is facilitated by mandatory registration on the Thai Chana mobile application (app) for everyone visiting a public venue, such as a restaurant or supermarket, or using public transport. The app records name and phone number for tracing if an index case is identified. The app traced 394 contacts in an incident on 10 July 2020, when a non-Thai index case violated regulations by visiting a shopping mall in Rayong province. All contacts were tested and quarantined for 14 days.

Clinicians, in particular critical care specialists, play an important role in the recovery of severely ill patients. Because of the limited feasibility of quickly mobilizing intensive care unit staff from relatively unaffected provinces to where they are urgently needed, all hospitals must always be prepared for an unpredictable epidemic. All public and private facilities with critical care capacity, such as intensive care beds and airborne infection isolation rooms (defined as having negative pressure, 6–12 air exchanges per hour, and a direct exhaust or high-efficiency particulate-air filter to the outdoors, are required to provide services, and health-care staff protect themselves by adhering to strict protocols.

The public health ministry instigated the relocation of acute respiratory infection patients to newly constructed shelter units outside the main hospital buildings to reduce their risk of contracting the virus. The ministry also developed standard operating procedures for all health facilities, such as management protocols for the acute respiratory infection clinic and wards containing less severely ill patients, as well as guidelines for the disinfection of all health-care settings.

Social interventions

Transparency builds trust and ensures compliance with social interventions. The Centre for COVID-19 Situation Administration has therefore communicated risk and engaged communities in its daily broadcast on all media channels since the beginning of the pandemic. The briefings consist of: an epidemiological update of the regional, national and global situation; the numbers of deaths and positive laboratory tests per million population; and the preventive measures that citizens are required to adopt.

Government policy to stay at home and work from home in April 2020 restricted the mobility of the population and contributed to the interruption of the virus transmission. In parallel, the government enforced the closure of public venues and banned social gatherings; security officers were responsible for monitoring and supporting adherence to these regulations.

A systematic review and meta-analysis has shown that physical distancing and the wearing of face masks are also effective in interrupting the transmission of SARS-CoV-2.29 Face masks protect others from speech-generated infected droplets from asymptomatic individuals. The high proportions of asymptomatic positive cases reported – for example, 50–75% in Italy and 78% in China – support the wearing of masks to prevent transmission. The Thai government's evidence-based strong recommendations have therefore included the wearing of a face mask, practising hand hygiene using alcohol gel, practising food hygiene by not sharing eating utensils or drinking vessels, and physical distancing. Although these measures are not mandatory, adherence by the general population is high; a local survey conducted during April 2020 reported that >90% of the population were following recommendations regarding the wearing of face masks.

Private sector construction of a new factory in just one month for the local manufacture and free distribution of N95 face masks (i.e. masks that filter at least 95% of airborne particles) to health-care facilities and the general public helped to meet the early demand for face marks. Local government departments mobilized communities

and volunteers to produce multilayer cloth masks. Although of lower efficacy, using cloth masks creates awareness and encourages respiratory hygiene. By the end of July 2020 there were 28 surgical mask factories operating in Thailand, producing 4.2 million masks daily.

The implementation of UHC ensures all Thai and non-Thai members of the public have access to prevention and curative services. Treatment for affected Thai citizens is financed by their respective insurance schemes; an additional government budget finances the treatment costs of all non-Thai patients, ensuring that there is no financial burden to anyone. The government allocated additional funding to enhance the capacity of certified laboratories in all provinces, provide laboratory testing, and cover the costs of food and lodging at 14-day quarantine sites for all Thai and non-Thai positive cases. The cost of active case detection using laboratory tests among high-risk and vulnerable communities, such as migrant workers, is also fully covered by the government.

Enhancement of response

To enhance the capacity of health-care workers to respond to COVID-19 and to protect all such workers from infection, three synergistic approaches were implemented from January 2020.

Surge capacity

A shortage of specialists, in particular intensive care nurses and critical care experts, became evident at the peak of epidemic. Some hospitals deployed experienced nurses from non-intensive care units within their own hospital or province to support the intensive care unit through on-the-job training. In provinces with a high case load and a critical shortage of health-care workers, medical teams were mobilized from other provinces. The public health ministry closely monitored the pandemic at a provincial level and managed the reallocation of resources.

At the peak of the pandemic in March 2020, all hospitals offered only essential emergency services. Clinical services for well-controlled noncommunicable diseases were transferred to primary care centres at a subdistrict level, protecting patients from the risk of potential infection during a hospital visit. These clinical services were supported by remote consultations and the dispensing of medicines by the postal service or private pharmacies. Such actions minimized the routine workload of health-care workers, allowing them to direct their resources towards treatment of patients diagnosed with COVID-19.

To support its huge workload, the Department of Disease Control mobilized experienced medical personnel and epidemiologists from provinces with any surplus capacity. The government deployed doctors, nurses and other health personnel to support quarantine sites with suspected positive cases. Local administrations mobilized one million existing village health volunteers to boost the capacity of the Surveillance and Rapid Response Teams for contact tracing. The new volunteers, recruited from local communities by the village head and the existing volunteers, received 43 hours of public health ministry-funded training in the district health office delivered by local public health personnel. In sharing the dialect, religion and sociocultural practices of local communities, village health volunteers were invaluable in challenging circumstances such as in the southern provinces, where many Muslim pilgrims were returning from other countries.

Occupational safety

The Department of Disease Control developed guidelines recommending that each hospital designate a team of health-care workers specifically for the COVID-19 ward, disallowing rotation to other wards. In some hospitals with severely ill COVID-19 patients, medical teams are divided into two groups – work and off-work, swapping over every 14 days – in case members of one team become infected and require 14-day quarantine.

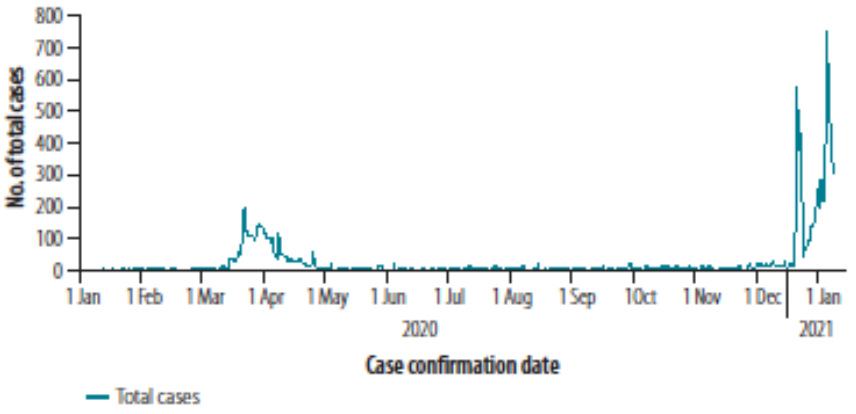
The public health ministry is also responsible for ensuring the occupational safety of health-care workers by providing adequate supplies of all types of personal protective equipment. However, public demand for personal protective equipment rose sharply in March 2020, leading to critical shortages in health facilities. After the publication of research demonstrating that sterilization of masks by ultraviolet radiation killed SARS-CoV-2,42 some health facilities recycled surgical masks. Plastic raincoats were used as personal protective equipment instead of surgical gowns for the screening of low-risk patients.

Isolation rooms for airborne infection were engineered by the Siam Cement Group and donated to hospitals for nasal swab and specimen collection to ensure the occupational safety of the medical team. Hospital staff deployed robots to deliver food and medicines to COVID-19-positive inpatients, and the use of remote communication and monitoring systems protected medical teams from exposure to the virus.

To ensure occupational safety for members of the Surveillance and Rapid Response Teams, all members with high-risk contacts are tested for SARS-CoV-2 and quarantined for 14 days regardless of the test result. Members with low-risk contacts are recommended to self-quarantine and work from home. If a health-care worker becomes infected, an outbreak investigation is conducted immediately to identify the possible source of infection and all contacts are traced for further action. Infection control specialists also developed a safety protocol for the team.

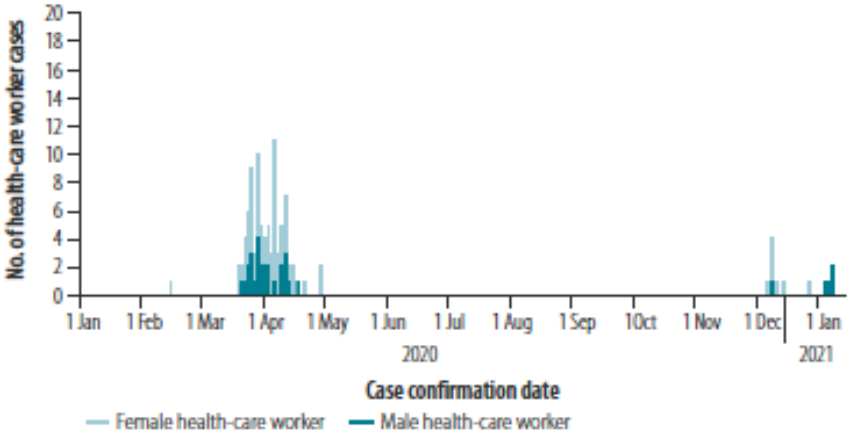
Morale and well-being

Fig. 1. **Number of COVID-19 cases among general population, Thailand, 1 January 2020–7 January 2021**



COVID-19: coronavirus disease 2019.

Fig. 2. **Number of COVID-19 cases among health-care workers, Thailand, 1 January 2020–7 January 2021**



COVID-19: coronavirus disease 2019

Both the government and the private sector initiated packages to support the morale and well-being of health-care workers. For example, the government approved 40,000 civil servant positions, upgrading all the contract employees, in particular nurses, to civil servant status. In Article 6(4) of the finance ministry 2018 regulation on compensation of health-care workers for adverse events, four types of events (death or permanent disability; loss of organ or disability; infection or serious occupation injury; or infection or injury requiring treatment for less than 20 days) are included. The cabinet approved the doubling of financial compensation to COVID-19-positive health-care workers who required treatment for less than 20 days from 50,000 Thai baht (1,670 United States dollars at the time of writing) to 100,000 Thai baht. An additional allowance per shift was approved for those working in hospitals or quarantine sites. Many insurance companies offered financial protection to all health-care workers against adverse events resulting from the treatment of COVID-19-positive patients in the form of premium-free indemnity coverage.

The prohibition of physical visits or care by family members for dying COVID-19-positive patients, replaced by a virtual presence through telecommunication, causes medical teams significant psychological trauma. Further, the strict infection control protocol means that family members are not allowed to closely approach or touch the dead body of their relative, a rule that is distressing for both visitors and health-care workers. However, the mental health department provides continual support to health-care workers in the form of a telephone helpline, where health-care workers can speak to qualified psychiatrists or psychologists.

Finally, health-care workers received national social recognition for their dedication to the pandemic response via the White Gown Hero/Heroine programme that was launched on live television on 29 March 2020 with 5 minutes of applause from citizens. The public have also been moved to donate food boxes and ready meals to health-care workers on duty at quarantine centres.

Effect of response

Of the 9636 COVID-19-positive cases as at 7 January 2021 (Fig. 1), 122 (1.3%) were health-care workers: 88 (72.1%) women and 34 (27.9%) men (Fig. 2). No health-care workers have died in Thailand as a result of the pandemic. Data collected between 22 July and 15 August 2020 in 37 countries show that the highest numbers of COVID-19-positive cases in health-care workers were reported in the USA (114,529 workers), Mexico (78,200 workers) and Italy (28,896 workers).[49] The highest numbers of deaths among health-care workers were reported in Mexico (1162 deaths), the USA (574 deaths) and Italy (214 deaths). Thailand ranked 65th out of 66 countries with more than 100 COVID-19-positive cases in health-care workers as at 8 May 2020.50

The policies that we have described here indicate that timely interventions minimize mortality. Combined, the function and quality of the Thai public health system, the

whole-of-government approach and effective risk communication to the public at the very early stage of the pandemic effectively contained transmission of the virus and prevented the health system from becoming overwhelmed.

Sri Lanka: The Carb Conundrum

Status, determinants and interventions on cardiovascular disease and diabetes in Sri Lanka: a desk review of research 2000 – 2018 -A joint publication by Ministry of Health, Nutrition and Indigenous Medicine and WHO Sri Lanka, highlighted the importance of prioritising issues pertaining to NCDs for research in the development of evidence-based interventions, with a view to translating these into action. The study noted that of the behavioural risk factors of CVD and DM, a drastic increase in sedentary behaviour has been seen over the years, especially related to diet and physical activity, It is shown that education provided is not well translated into healthy practices, owing to cultural barriers and poor motivation. It was revealed that 71% of the total dietary energy is from carbohydrates, with the number of starch portions well-above the national recommendation. Thus, empowerment through health promotion may exceptionally help in this regard.

This article was prepared by **Y Mapalagama**, for the Students Involved in Rational Health Activities (SIRHA)- a group of Sri Lankan medical students dedicated to increasing awareness of rational health care.

Acknowledgement – Heartfelt gratitude is extended to Prof. Ranil Jayawardena for the guidance.

An observation on the issue of disproportionate carbohydrate servings at major meals in Sri Lanka

The main purpose of this article is to identify the problems concerning Carbohydrates in the average Sri Lankan meal.

The Issue

Remember the young days when we wrote essays about our wonderful motherland? That one sentence 'rice is the staple meal of Sri Lanka' sadly brings up many red flags now. We do have a wonderful cuisine, variety of fruits and vegetables, and an abundant supply of leafy greens and spices. Despite the available food, an average Sri Lankan meal has slowly become more and more carbohydrates and not much of anything else.

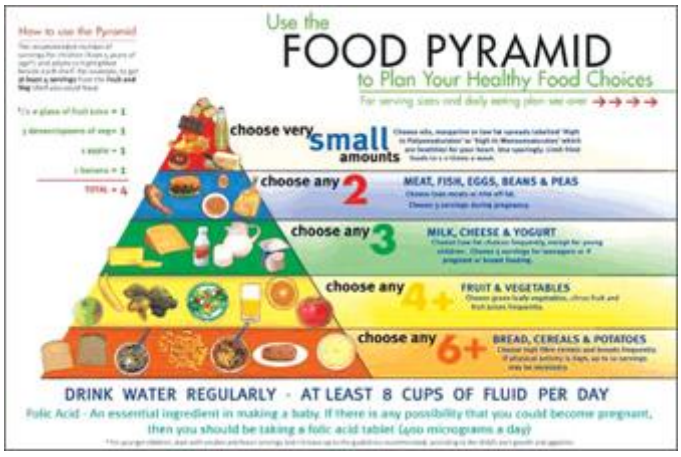
If one day we go off rice, we turn into hoppers, string hoppers, koththu, pittu, roti, bread, noodles, manioc, sweet potatoes, bread fruit even that occasional pizza. And what do they all have in common? The major portions are carbohydrates. Though we eat various curries, the trouble is not in the food itself but in our food habits.

Another problem would be that processing cereals to make flour and polishing rice has led a major waste of nutrients. Majority of the vitamins in rice and other pulses are found on the outer surface of the grain. These pulses are polished, processed or milled as an attempt to refine them. It is to be noted that most of the Vitamin B is lost during these processes.

While traditional Sri Lankan diets remains constant, the sedentary lifestyle has caused a large surplus in the calory intake. The ratio of carbohydrates to proteins and vegetables is rather skewed in the average Sri Lankan meal. While at least a fraction of the population is somewhat conscious about consuming proteins, dairy, fruits and vegetables (due to the awareness about the concept of balanced meals), the same can't be said regarding the serving sizes of carbohydrates. The serving sizes would not be a problem without the inactive and sedentary lifestyle.

An explanation

The average Sri Lankan meal is a large amount of rice surrounded by a small amount of curries. Unfortunately, this ratio is nowhere near the proportions recommended in the national food pyramid guidelines for Sri Lankans. (Jayawardena et al, 2013) And this not just for one meal! Most Sri Lankans consume the largest starch portion for



lunch or dinner and have three meals per day – all dominated by carbohydrates. Even though lentils, pulses, yams are also used as curries, it should be remembered that they do contain a considerable ratio of carbs too. Sri Lankans consume large numbers of starch servings; nearly 65% consumed well above the upper cutoff of the recommendations from the Sri Lankan food pyramid guidelines. (Jayawardena et al, 2013)

Effect

Unfortunately, even though consumption of large portions of rice and other carbs are considered a daily necessity by the general population, the high glycaemic Index of rice and foods made from processed flour is not very forgiving. The population is slowly being swallowed up by Diabetes Mellitus - which is gaining epidemic status - and other related non-communicable diseases. It appears to be possible to suspect a partial influence by this issue.

Recommendations

Given the current situation, especially when exercise and adjustment of physical activity is inadequate dietary intervention has become a must.

It should be noted that unprocessed cereals have a large fibre content and are extremely beneficial. Controlling the fibre content in food is important because the higher the amount of natural fibre the higher the satiety. They also reduce the rate of absorption of sugars and cholesterol. Perhaps the reason for larger portion sizes than normal would be the need to be satisfied. Natural fibres in a meal are more satisfying. Control of portion sizes in a dietary intervention has been recorded as a successful model of dietary intervention. (Jayawardena et al, 2019)

However, during steaming of paddy, some of the vitamins in the periphery of the grain travel to the centre and therefore parboiled rice is more beneficial than refined raw rice, when it comes to the nutrients. Milling during the process of producing wheat flour takes away a lot of fibre and nutrients (specially Vitamin B).

As a recap, the amount of carbohydrates consumed should reflect on the individual's level of physical activity, person's age, gender and physiological state. The population should be addressed in a more effective way to solve the unnecessarily high daily intake of carbs in Sri Lanka and to emphasize the value of proper serving sizes. The concepts of proper technique in food preparation when combining carbs and other food group also need to be popularized. The burden of NCDs on the Sri Lankan healthcare system would rise exponentially in the future if such issues are left unaddressed.

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NYU TLP Clinic Report on NIH's 070 Patent –

Moderna is using a US NIH patent and therefore there is the possibility of pushing Moderna to share the 'technical know how' so that LMIC manufacturers can make the vaccine.

The technology described and claimed in the '070 patent is not new and fundamental to the design of many of the world's leading COVID-19 vaccines. One such vaccine is mRNA-1273,which is manufactured by the U.S.-based pharmaceutical company Moderna, Inc. (Moderna).The mRNA-1273vaccine is widely described as 'Moderna's' vaccine, although some have challenged this characterization, pointing to the enormous public investment made in its research, development, manufacture, and distribution—by the U.S. government first and foremost. As a vaccine, mRNA-1273 has uniquely valuable properties, including stability during storage, scalability, and suitability to serve as a platform for development of vaccines effective against new variants. These properties of mRNA-1273, along with the U.S. government's unprecedented investment in its development, have led many civil society groups, including PrEP4All and Public Citizen, to call on Moderna to share its intellectual property covering mRNA-1273—Moderna's patents, trade secrets, samples of intermediates used in its manufacturing process, and so on—with the world. Moderna has thus far resisted those calls.

NYU TLP Clinic Report on NIH's 070 Patent
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